



March 19, 2026

Administrator Mehmet Oz
Centers for Medicare & Medicaid Services
P.O. Box 8010
Baltimore, MD 21244–1850.

Re: Ensuring Safety Through Domestic Security with Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals [CMS–1516–ANPRM]

Dear Administrator Oz,

On behalf of the End Drug Shortages Alliance (EDSA), thank you for the opportunity to provide input in response to the Centers for Medicare & Medicaid Services' (CMS) request for public input on strengthening the domestic supply chain for personal protective equipment (PPE) and essential medicines. EDSA is a multi-stakeholder alliance representing manufacturers, distributors, health systems, group purchasing organizations, clinicians, and patient advocates, all united around a common goal: ending drug shortages and ensuring reliable patient access to essential medicines.

EDSA strongly supports the Administration's focus on supply chain resilience and national preparedness. At the same time, we urge CMS to take a targeted and economically sustainable approach to domestic manufacturing policy.

In response to strong price competition in the U.S. generic drug market, generic products rely on highly globalized and lean supply chains where economies of scale and lower operating costs allow manufacturers to remain economically viable. In market segments where pricing levels are low relative to manufacturing complexity, economic constraints may further reduce incentives for manufacturers to invest in redundancy, facility modernization, or geographically diversified production capacity - investments that are often necessary to support supply chain resilience and reliable access to essential medicines.

Indeed, drug shortages in the United States most frequently affect generic medicines, particularly sterile injectable products used in hospital and acute care settings. Analyses from organizations such as the U.S. Pharmacopeia (USP) consistently show that medicines most vulnerable to shortage tend to share several characteristics: low cost, complex manufacturing processes, limited manufacturer participation, and concentrated supply chains.

Ensuring reliable access for patients will require policies that recognize the economic conditions influencing sustained manufacturer participation and supply chain resilience. EDSA recommends that CMS consider policy levers that support long-term market sustainability.

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Economic and Market Sustainability for Reliable Domestic Manufacturers

Domestic manufacturing location alone does not necessarily guarantee supply reliability, as both reliable and unreliable manufacturers may operate within the United States. In the near term, in addition to domestic production volume, CMS should structure incentives that reward investments around clearly defined supply reliability attributes, such as redundant capacity, buffer supply, surge readiness, and quality management maturity to align incentives with outcomes that reduce shortage risk.

As a longer-term evolution, CMS should consider additional incentives tied to voluntary participation in third-party supply chain reliability benchmarking program. Three prominent examples of such programs include HIRC's Resiliency Badging Program, US Pharmacopeia's Drug Supply Chain Resilience Benchmarking Program, and FDA's Quality Management Maturity Program. Over time, as benchmarking frameworks converge and mature and industry participation increases, such assessments could provide valuable, comparable insights for purchasers into supplier reliability and performance history.

Secure American Medical Supplies Hospital Designation

EDSA appreciates that CMS has advanced this framework as an incentive-based approach. Explicit clarification that participation is voluntary would further reinforce the collaborative intent of the program. Hospital purchasing decisions are typically made at the enterprise level and are influenced by multi-year contracts, clinical considerations, and supply availability. Clear confirmation that the program is designed to encourage participation rather than require compliance may support broader adoption and implementation.

Relatedly, EDSA suggests that a binary attestation approach tied to a single domestic procurement threshold may not fully capture the complexity of hospital purchasing environments. Health systems often face supply variability across product categories and contractual commitments that evolve over time. An all-or-nothing designation could unintentionally discourage participation by hospitals that are making meaningful progress toward domestic sourcing but cannot consistently meet a single threshold across all products. CMS may wish to consider a graduated or tiered framework that recognizes incremental progress toward domestic procurement and supply chain resilience. Such an approach could provide more meaningful transparency into adoption trends while encouraging continued participation as domestic manufacturing capacity expands.

Payment Methodology

CMS has appropriately recognized the higher resource costs associated with procuring domestically manufactured essential medicines. However, the approach in this ANPRM accounts only for Medicare's share of those incremental costs. Because procurement decisions are typically made across the hospital enterprise rather than for Medicare beneficiaries alone, hospitals may still absorb a substantial portion of the marginal cost associated with domestic sourcing. This enterprise-level cost exposure could limit participation and dilute the intended incentive signal.

To effectively catalyze new domestic investment, EDSA encourages CMS to ensure that incentives supporting domestic sourcing are not implemented in a budget-neutral manner. Strengthening domestic manufacturing capacity will likely require higher prices for certain low-cost generic medicines, particularly sterile injectables that have historically experienced limited investment. If incentives are funded through redistribution within existing reimbursement structures, hospitals may

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be expected to absorb these higher acquisition costs, which could further limit participation. Additive funding mechanisms would more effectively support domestic manufacturing goals and reinforce the program's objective of strengthening supply chain resilience.

EDSA also encourages consideration of how cost differentials are paired with measures of supply vulnerability. A reimbursement adjustment that reflects cost spread alone may not fully align incentives with resilience objectives. Some products may have relatively high-cost differentials but low historical shortage risk, while others with modest price differences may face significant supply concentration or manufacturing fragility. Incorporating vulnerability indicators alongside cost considerations may help ensure incentives are directed toward medicines where resilience investments are most likely to reduce shortage risk.

If CMS proceeds with a standardized national unit-cost differential methodology, consideration should be given to both alignment with real-world acquisition patterns and the operational burden placed on hospitals. Because inpatient drugs are reimbursed through bundled IPPS payments and cost reporting occurs at an aggregate level rather than the NDC level, a generalized national differential may not perfectly reflect hospital-specific marginal acquisition costs. However, requiring hospitals to independently calculate product-specific cost spreads would introduce significant administrative burden. CMS may therefore wish to rely on manufacturer-reported or other centralized pricing data - consistent with existing Part B payment methodologies - while acknowledging that any national methodology represents an approximation of hospital purchasing economics. A transparent, predictable, and consistently applied methodology would help minimize administrative complexity and preserve the intended incentive effect.

While modifications to the Medicaid Drug Rebate Program and related rebate structures would require legislative action beyond CMS's authority, these policies may materially affect the economic feasibility of domestic manufacturing investments. As CMS evaluates payment and procurement strategies, alignment across reimbursement and rebate policies will be critical to avoid unintended disincentives to domestic investment and to support long-term supply chain resilience.

Subcategorized Approach

In addition to broader market dynamics, **pediatrics and other special population medicines** face unique structural and economic vulnerabilities that warrant explicit consideration within resilience policy design. These products often serve small patient populations, are manufactured in low volumes, and may lack clinically appropriate substitutes. Pediatric patients often require unique formulations of essential drugs, underscoring the need for domestic production incentives that specifically stabilize pediatric versions. For example, the pediatric formulation of albuterol is generally appropriate for adults, but the adult formulation is unsuitable for children because of its higher dose and delivery strength.

Reimbursement mechanisms should account for the higher per-unit costs associated with pediatric products, as enterprise-level cost exposure may otherwise deter domestic sourcing. In addition, CMS may wish to recognize that for many pediatric formulations, domestic finished-dose capacity and prioritization, rather than API availability alone, represents the primary determinant of supply continuity. Explicit incorporation of pediatric-specific vulnerability factors within designation and incentive frameworks would help ensure resilience policies effectively support this clinically critical population.

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Generic sterile injectable medicines illustrate many of the structural vulnerabilities identified by USP, including low price points, complex manufacturing requirements, limited manufacturer participation, and concentrated supply chains, contributing to their disproportionate representation among drug shortages. Data from the American Society of Health-System Pharmacists (ASHP) indicate that generic sterile injectable medicines account for approximately 69 percent of active drug shortages, underscoring the structural fragility of this segment of the market. Because these medicines are widely used in hospital and acute care settings - including emergency departments, intensive care units, and oncology care – prioritizing policies designed to strengthen domestic manufacturing capacity, supply reliability, and economic sustainability for these high-risk medicines may help ensure that program incentives are aligned with the areas of greatest shortage vulnerability and patient impact.

Defining and Identification of “Domestic Manufacturing”

As CMS considers policy options related to domestic procurement, designation criteria, and potential reporting or attestation requirements, greater clarity around what constitutes “domestic manufacturing” will be important for both hospitals and manufacturers. Clear differentiation and thresholds across the stages would help more accurately assess procurement options under any potential designation or payment framework. Absent clear guidance or an authoritative product list, hospitals face significant challenges independently verifying domestic content across complex, multi-tier supply chains. Requiring hospitals to trace upstream sourcing or validate supplier representations would increase administrative burden and create variability in interpretation across institutions.

EDSA encourages CMS to develop a centralized or federally recognized approach to identifying “qualified” domestic suppliers that would reduce administrative burden for purchasers and improve consistency. CMS could, for example, publish and periodically update a list of eligible domestic products, allowing hospitals and purchasers to align procurement decisions with clearly identified products that meet defined domestic criteria. If CMS establishes a centralized list of eligible domestic products, it will be important to provide clear eligibility duration parameters. Hospitals should not make procurement decisions based on a product’s qualification status only to have that designation removed shortly thereafter. CMS could consider defined eligibility periods (e.g., multi-year qualification windows), advance notice of designation changes and clear transition timelines.

A centralized list or qualified supplier framework also provides greater transparency for manufacturers seeking to participate in domestic procurement initiatives while reducing duplicative verification efforts across the healthcare system.

We also encourage CMS to work with interagency partners to align definitions and incentives so that manufacturing strategies address upstream concentration risks, while recognizing that full end-to-end domestic production may not be achievable or necessary for every product. Hybrid models, such as diversified API sourcing combined with domestic finishing for the most vulnerable products, may offer resilience benefits with lower cost and faster implementation.

Experience across the pharmaceutical supply chain shows that over-reliance on any single geography - whether domestic or foreign - can increase exposure to disruptions from natural disasters, geopolitical events, quality failures, and market exits. Domestic manufacturing can reduce specific vulnerabilities, but it is most effective when integrated into a broader diversification strategy that also considers supply reliability and performance history.

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Policies that balance domestic investment with economic viability and reliability considerations are more likely to strengthen continuity of care, preserve competition, and avoid unintended disruptions than approaches that simply shift concentration risk from one geography to another.

Within this context, EDSA encourages CMS to consider a tiered incentive structure that reflects varying levels of domestic supply chain depth and feasibility:

- Tier 1 – U.S.-based finished dosage form production: Initial incentives could prioritize medicines where the final drug product, including fill-finish, testing, and release, is manufactured in the United States. This represents the most immediate viable pathway for scaling domestic production and activating existing capacity. *Analysis from the API Innovation Center (APIIC) excess capacity survey in 2022 indicates that U.S. generic manufacturers are operating at roughly 50% utilization, with nearly 30 billion additional doses of essential medicines able to be produced using existing infrastructure.* Leveraging this underutilized, FDA-approved capacity offers a near-term, cost-effective opportunity to expand domestic supply without the long lead times required to build new facilities.
- Tier 2 – Integrated domestic finished goods and API production (i.e. Tier 1 + API): Enhanced incentives could apply where both the finished dosage form and a meaningful portion of the active pharmaceutical ingredient(s) (API) are manufactured domestically. This tier would recognize the additional investment required to reduce upstream foreign dependency and concentration risk, particularly for high-vulnerability essential medicines.
- Additional reliability incentive – As discussed above, reliability assessment frameworks are still evolving and would require further investment, harmonization, and industry participation before serving as a durable foundation for payment policy. Accordingly, for products that qualify for either Tier 1 or Tier 2, CMS should consider a future additional reliability incentive tied to voluntary participation in recognized supply chain reliability benchmarking programs. Structuring this as a voluntary, future phase would allow CMS to encourage measurable reliability performance over time while preserving near-term feasibility and minimizing administrative burden. In the near-term, CMS and other federal government entities should explore avenues to work with the private sector to encourage development, piloting, and adoption of supply chain reliability assessment programs that could potentially form the foundation for this future reliability incentive.

A tiered approach would allow CMS to encourage near-term activation of domestic finished-dose capacity while creating stronger signals for longer-term reliability, upstream diversification and reshoring.

Conclusion

EDSA applauds CMS for engaging stakeholders in this important discussion and encourages CMS to consider how program design can most effectively encourage participation while minimizing administrative burden and aligning incentives with real-world hospital purchasing dynamics.

Program designs that **encourage incremental participation, maintain administrative feasibility, and align incentives with real-world procurement behavior** may be more likely to support the long-term goals of strengthening domestic manufacturing capacity and improving supply chain resilience.

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We urge CMS to pursue a targeted approach to domestic manufacturing, one that prioritizes the most vulnerable medicines, patient continuity of care, clearly defines domestic production, and embeds economic sustainability and resiliency at its core.

EDSA stands ready to collaborate with CMS and federal partners by sharing insights from our pilots, committees, and multi-stakeholder membership to help inform practical, actionable strategies that strengthen the supply of essential medicines while safeguarding patient care.

Respectfully submitted,

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